REMARKS

Claims 1, 8, 14, 17 and 23 are amended and Claims 4, 9-11, 18-20, and 24-26 have been cancelled. Thus, Claims 1-3, 5-8, 12-17, 21-23 and 27- 31 remain presented for examination. Claims 27 and 28 are indicated as allowable.

Discussion of Rejections under 35 U.S.C § 112, Second Paragraph

Claims 1, 8, 17, and 23 stand rejected under 35 U.S.C. §112, second paragraph, as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse.

The Examiner maintained his rejection of the term "homology". As previously argued, Applicants reiterate that the term homology is well-known to those of ordinary skill in the art to mean "corresponding or similar in position, value, structure, or function" (The American Heritage® Dictionary of the English Language, Fourth Edition). Moreover, the specification contains a detailed explanation of calculating homology using well-known programs, such as BLAST. See page 9, beginning with line 21.

However, solely to advance prosecution of the application, Applicants have amended the claims to replace "homology" with the term "sequence identity", as suggested by the Examiner. Accordingly, Applicants respectfully request withdrawal of this rejection.

Discussion of Written Description Rejections under 35 U.S.C § 112, First Paragraph

Claims 1-3, 5, 8, 12, 15-17, 21, 23 and 29-31 stand rejected under 35 U.S.C. § 112, first paragraph because the specification allegedly did not provide a sufficient written description of the claimed invention. The Examiner argues that the domains that Applicants recited for the DAS5 protein are characteristic for all P450 family members and not specific to Applicants' DAS5 protein. In addition, the Examiner maintains that no common function or structure is recited for sequences having 95% homology with DAS5. Applicants respectfully disagree.

In order to meet the written description requirement, Applicants are only required to show that their patent application describes the claimed invention in sufficient detail so that one of ordinary skill in the relevant art would conclude that the inventor was in possession of the claimed invention at the time the application was filed. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, (Fed. Cir. 1991).

In this case, the claimed invention relates to genetically modified plants, seeds, and methods of making such plants by transformation with a nucleic acid that encodes an amino acid sequence having at least 95% sequence identity to SEQ ID NO: 1. Applicants' specification provides specific evidence that the inventors were in possession of this invention. For example, the specification provides detailed information on the identification and sequence analysis of the DAS5 nucleic acid sequence (Example 2, page 35, lines 10-26; and Example 3, page 35, line 27 to page 36, line 11). Furthermore, the specification provides a complete and detailed description of methods for producing genetically transformed plants (page 20, line 20 to page 27, line 14, "GENE TRANSFER TO PLANTS" and Example 1, page 34, line 1 to page 35, line 8). The specification also teaches how to screen for plants having increased yield (page 30, line 13 to page 32, line 4). The specification further teaches genetically modified seeds (page 28, lines 14 to 25). In addition, Applicants describe that embodiments of their invention include modified polypeptides that have the biological activity of DAS5, including increased yield (page 8, lines 2-4). Applicants state that DAS5 polypeptides include conservative variations of the polypeptide sequence of SEQ ID NO: 1 (page 8, lines 14-24). Finally, Applicants explicitly state that their invention includes polypeptides having at least 95% homology with the amino acid sequence shown in SEQ ID NO: 1 (page 8, line 29). These passages from the specification would lead one of ordinary skill in the art to conclude that Applicants were in possession of the claimed invention at the time the application was filed.

Applicants further disagree with the Examiner's erroneous assertion that no function or structure is recited with the "95% homology" sequences. The present claims recite a common function for all of the DAS5 sequences within the scope of "95% identical to SEQ ID NO: 1", that is, DAS5 nucleotide sequences transformed into plants, result in plants that have increased yield in comparison to wild-type plants. Indeed, the function of increased yield by the DAS5

sequences was recognized only by Applicants. The specification teaches that plants transformed with a nucleic acid encoding the amino acid sequence of SEQ ID NO: 1 results in plants that have an increased yield in comparison to wild-type plants (page 1, lines 13-15; page 6, line 29-30; page 30, line 3). The specification also teaches that the term "yield" refers to "increased plant growth, increased crop growth, and or increased biomass production" (page 8, lines 5-8). Thus, the common function for all of the sequences within the scope of "95% identical to SEQ ID NO: 1" is that their transformation into plants results in a plant with increased yield.

Applicants' pending claims and their support are analogous to the claims and support in Example 9 from the U.S.P.T.O. written description guidelines, which were found to be adequately supported by the description in the specification (66 Fed. Reg 1099 issued on January 5, 2001). In that Example, the exemplary claim recites "[a]n isolated nucleic acid that specifically hybridizes under stringent conditions to the complement of the sequence set forth in SEQ ID NO: 1..." Only a single species (SEQ ID NO: 1) is disclosed in the example. The Patent Office concluded that the written description requirement was met. The disclosure of a single nucleic acid sequence was a sufficient number of species, since the highly stringent hybridization conditions, in combination with the coding function of DNA and the level of skill and knowledge in the art, were adequate to determine that applicant was in possession of the claimed invention.

For the same reasons as are cited in Example 9, a person of skill in the art would expect a common structure among species of nucleic acids that expresses an amino acid sequence having at least 95% sequence identity to SEQ ID NO: 1 and function to increase the yield of plants. This is due to the high sequence identity claimed for the sequences. Thus, Applicants disclosure of a single sequence is adequate to determine that the Applicants were in possession of the claimed invention.

Applicants therefore request the withdrawal of the written description rejection and allowance of Claims 1-3, 5, 8, 12, 15-17, 21, 23 and 29-31.

Discussion of Enablement Rejections under 35 U.S.C § 112, First Paragraph

The Examiner rejected Claims 1-3, 5, 8, 12, 15-17, 21, 23 and 29-31 under 35 U.S.C. 112, first paragraph. The Examiner argued that screening through a multitude of sequences from a multitude of plants would constitute undue experimentation. Applicants respectfully traverse.

Several factors need to be considered to properly determine whether the specification enables one of ordinary skill in the art to practice the claimed invention without undue experimentation (*In re* Wands, 858 F.2d 731, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988)). These factors include: 1) the quantity of experimentation necessary; 2) the amount of direction or guidance presented in the application; 3) the presence or absence of working examples of the invention in the application; 4) the nature of the invention; 5) the state of the prior art; 6) the relative skill of those in the art; 7) the predictability or unpredictability in the art; and 8) the breadth of the claimed invention.

It should be noted that a considerable amount of experimentation is permissible, if it is merely routine (*Ex parte* Jackson, 217 U.S.P.Q. 804, 807 (B.P.A.I. 1982). In addition, experimentation can be "tedious and laborious," and nevertheless "routine" (*Ex parte* Erlich 3 U.S.P.Q.2d 1011 (B.P.A.I. 1982). Experimentation requiring only routine optimization or screening has not been held to be undue experimentation because "[e]nablement is not precluded by the necessity for some experimentation such as routine screening" (In re Wands).

With respect to factors one, two and three, the quantity of experimentation necessary, the amount of direction or guidance presented in the application; and the presence or absence of working examples of the invention in the application; the specification discloses with great specificity how to perform such screening techniques and little experimentation is necessary (page 20, line 20 to page 27, line 14, "GENE TRANSFER TO PLANTS" and Example 1, page 34, line 1 to page 35, line 8). Numerous methods to transform plants with nucleotides and an exemplary method are provided. While some routine laboratory work may be needed, an undue amount of experimentation is not needed. Accordingly, the amount of guidance provided by the specification is very high. Moreover, actual working examples of transforming and screening a

large number of plants are provided by the specification. Thus, these factors also fall in favor of the Applicants.

With respect to factors four and five, the nature of the invention and the state of the prior art; one of skill in the art would be able to practice the claimed invention without undue experimentation. The nature of this invention relates to genetically modified plants, seeds, and methods of making such plants by transformation with a nucleic acid that expresses an amino acid sequence having at least 95% sequence identity to SEQ ID NO: 1. While plant biology may be complex, the actual methods of transforming and screening plants in order to generate genetically modified plants are well-known and practiced by skilled molecular plant biologists. Furthermore, the prior art is replete with a variety of techniques for producing genetically modified plants and numerous references describing transformed plants. Accordingly, this factor falls in favor of the Applicants.

With respect to factor six, the relative skill of those in the art, screening hundreds, or even thousands, of plants is well within the skill of the ordinary plant molecular biologist. In order to practice invention methods directed to transformed plants that had increased yield in comparison to wild-type plants, one would only need to grow such transformed plants and then screen for those transformed plants with an increased yield. Indeed, Example 1 of the specification indicates that "several thousand *Arabidopsis* plants" were screened by the inventors to find in the initial mutant (page 34, line 3). Accordingly, while the quantity of experimentation for such a screen may be high, it would nonetheless be routine experimentation. This factor, therefore falls in favor of the Applicants.

With respect to factor seven, the predictability or unpredictability in the art, as is known and well documented, the level of skill in the area of biotechnology is quite high. And although some areas of biotechnology may be unpredictable, methods of transforming and screening plants are not unpredictable. This is especially true when, as in the present case, one has already disclosed the function of a gene used to transform the plants and now only needs to screen for plants that exhibit the known function. Thus, this factor falls in favor of the Applicants.

With respect to factor eight, the breadth of the claimed invention, Applicants claims are well within the scope of the disclosure. Applicants are only claiming a well-defined genus, namely genetically modified plants, seeds, and methods of making such plants by transformation with a nucleic acid that expresses an amino acid sequence having at least 95% sequence identity to SEQ ID NO: 1. One of ordinary skill in the art can easily know the metes and bounds of such a claim as it is straightforward to determine whether or not a particular nucleic acid encodes an amino acid sequence that is at least 95% identical to SEQ ID NO: 1. In addition, it only requires routine experimentation to screen plants transformed with these nucleic acids to determine which plants exhibited an increased yield. Thus, this factor falls in favor of the Applicants.

By application of the Wands factors, it is clear that undue experimentation is not required to make and use the claimed invention. Thus, Applicants respectfully request withdrawal of all rejections under 35 U.S.C. § 112, and allowance of the pending application.

CONCLUSION

Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, amendments to the claims, the reasons therefor, and arguments in support of the patentability of the pending claim set are presented above. Any claim amendments which are not specifically discussed in the above remarks are made in order to improve the clarity of claim language, to correct grammatical mistakes or ambiguities, and to otherwise improve the capacity of the claims to particularly and distinctly point out the invention to those of skill in the art. In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410. If the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, the Examiner is respectfully requested to initiate the same with the undersigned.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: February 3, 2004

By: _____

Michael L. Fuller
Registration No. 36,516
Attorney of Record
Customer No. 20,995
(619) 235-8550

[S:\DOCS\MLF\MLF-8062.DOC
010804]
S:\DOCS\MLF\MLF-8062A.DOC
020204